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| APPLICATION NO.          | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.   | CONFIRMATION NO. |
|--------------------------|-------------|----------------------|-----------------------|------------------|
| 09/909,244               | 07/19/2001  | Ton Logtenberg       | 5016US                | 8655             |
| 24247                    | 7590        | 03/08/2004           | EXAMINER              |                  |
| TRASK BRITT              |             |                      | BELYAVSKIY, MICHAIL A |                  |
| P.O. BOX 2550            |             |                      | ART UNIT              | PAPER NUMBER     |
| SALT LAKE CITY, UT 84110 |             |                      | 1644                  |                  |

DATE MAILED: 03/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |   |  |  |
|------------------------------|---|--|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>09/909,244    | <b>Applicant(s)</b><br>LOGTENBERG ET AL. |  |
|                              | <b>Examiner</b><br>Michail A Belyavskiy | <b>Art Unit</b><br>1644                  |  |

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 19 July 2001.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-9, 11-21 and 24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-9, 11-21 and 24 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

1. The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

*Misnumbered claims 20 – 23 have been renumbered as claims 21-24, respectively.*

2. Applicant's amendments, filed 07/19/2001 is acknowledged.

3. Claims 1- 9, 11-21 and 24 are pending.

### ***Restriction Requirement***

4. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

- I. Claims 1-9, drawn to a binding molecule capable of selectively binding to a subset of CD38 proteins, classified in Class 530, subclass 387.1.
- II. Claims 11-20, drawn to a method of treating an individual suffering from a tumor of the lymphoid lineage, classified in Class 424, subclasses 139.1 and 93.7
- III. Claims 11-19, drawn to a method of treating an individual suffering from an autoimmune disease, classified in Class 424, subclasses 139.1 and 577 .
- IV. Claims 11-19, drawn to a method of treating an individual suffering from an infection with a pathogen, classified in Class 424, subclasses 139.1 and 184.1 .
- V Claim 21 drawn to method for marking a CD38 expressing cell, classified in Class 424, subclasses 139.1, 93.7 and 577; 435, subclasses 7.1 and 326
- VI Claim 24 , drawn to a method of selecting a binding molecule to a CD38 epitope, classified in Class 435, subclass 7.1;

5. Groups II- VI are different methods. These inventions are different with respect to ingredients, method steps, etiologies and therapeutic endpoints of pathological conditions which require non-coextensive searches ; therefore, each method is patentably distinct.

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6. Groups I and II-V are related as product and process of using. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case a binding molecule of Group I can be used for affinity purification, in addition to the methods of treating and marking recited.

7. These inventions are distinct for the reasons given above. In addition, they have acquired a separate status in the art as shown by different classification and/or recognized divergent subject matter. Further, even though in some cases the classification is shared, a different field of search would be required based upon the structurally distinct products recited and the various methods of use comprising distinct method steps. Moreover, a prior art search also requires a literature search. It is an undue burden for the examiner to search more than one invention. Therefore restriction for examination purposes as indicated is proper.

### **Species Election**

8. Applicant is further required under 35 USC 121 (1) to elect a single disclosed species to which the claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

9. If Group I is elected, applicant is required to elect a specific binding molecule capable of selectively binding to a subset of CD38 proteins wherein: (i) a specific subset of cells is selected from the group recited in claims 3 and 6.

10. If one of the Groups II - IV is elected, applicant is required to elect a specific method of treating an individual suffering from a disease, wherein a specific subset of cells is selected from the group recited in claims 13 and 16.

These species are distinct because a specific method of treating an individual suffering from a disease, wherein a specific subset of cells is selected from the group recited in claims 13 and 16 differ with respect to the specific subset of cells thus each specific method employing a specific subset of cells represents patentably distinct subject matter.

11. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

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Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

12. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

13. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement can be traversed.


A telephone call was made to Allen C. Turner on 3/4/04 to request an oral election to the above restriction requirement, but did not result in an election being made.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michail Belyavskiy whose telephone number is 571/ 272-0840. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571/ 272-0841.

The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michail Belyavskiy, Ph.D.  
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March 3, 2004

  
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